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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,975

06/09/2005

Yves Jongen

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EXAMINER

PALABRICA, RICARDO J

ART UNIT

PAPER NUMBER

3663

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,975	<b>Applicant(s)</b> JONGEN ET AL.	
	<b>Examiner</b> Rick Palabrica	<b>Art Unit</b> 3663	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008 and 18 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,13,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,10-12,14,15,21-26 and 29-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/9/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's election without traverse of Group I (combination apparatus), species A (pump flow rate greater than 200 ml/min in the reply filed on 4/17/08, and species D (embodiment shown in Figs. 5-7) in the reply filed on 7/18/08, are acknowledged.

Based on applicant's election, claims 1-7, 10-12, 14, 15, 21-26 and 29-31 are examined in this Office action. Claims 8, 9, 13, 27 and 28, which are directed to the non-elected invention, are removed from consideration.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the helium-based cooling device for cooling the irradiation window (see claim 15) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

Art Unit: 3663

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23-26 and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation, "a cavity for receiving the target fluid located between the lateral wall, second wall portion and irradiation window." Underlining provided.

The claim is vague, indefinite and incomplete, and its metes and bounds cannot be determined because it can be interpreted in many different ways, e.g., the cavity is between the lateral wall and the second wall portion, the cavity is between the second wall portion and the irradiation window, etc.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Kiselev et al. (U.S. 6,567,492) or Stanton (U.S. 3,349,001) or Amini (U.S. 6,917,044) or under 35 U.S.C. 102(a) as being anticipated by Wieland et al. (U.S. 7,200,198).

Kiselev et al.

Kiselev discloses a device for producing fluorine-18. As to claims 1 and 21, applicant's claim language reads on Kiselev et al. (see Fig. 1) as follows a) irradiation cell with a metallic insert and a cavity" reads on target 11 having a silver body with a target volume behind an aperture (see also col. 3, lines 57+); b) "pump" reads on pump 13; c) "external heat exchanger" reads on cooling coil 23; c) "pressurizing device" reads on helium tank 43.

Stanton

Stanton discloses a device that inherently produces radioisotopes from irradiation of a target fluid (molten lead) by protons. As to claims 1 and 21, applicant's claim language reads on Stanton (see Fig. 1) as follows a) irradiation cell with a metallic insert and a cavity" reads on fluid transition column 31 having a metallic insert (i.e., molten lead) and a cavity; b) "pump" reads on electromagnetic pump 24; c) "external heat

Art Unit: 3663

exchanger” reads on heat exchanger 30; c) “pressurizing device” reads on heating means 23a that inherently raises the temperature and corresponding pressure in the system.

Amini

Amini discloses a device having a high power, high yield target for production of fluorine-18. As to claims 1 and 21, applicant’s claim language reads on Amini (see Fig. 1) as follows a) irradiation cell with a metallic insert and a cavity” reads on the combination of cooling flange 31 and target body 11; b) “pump” reads on the inherent pump for pumping the target fluid into cavity 10; c) “external heat exchanger” reads on heat sink 19 (see also col. 7, lines 1+); c) “pressurizing device” reads on heaters that inherently raise the temperature and corresponding pressure in the system (see also col. 7, lines 39+).

Wieland et al.

Wieland et al. disclose a device for producing radionuclides, including fluorine-18. As to claims 1 and 21, applicant’s claim language reads on Wieland et al. (see Fig. 1) as follows a) irradiation cell with a metallic insert and a cavity” reads on target assembly TA having a target body 12 constructed from silver (see also col. 3, lines 57+); b) “pump” reads on pump section PS having a regenerative turbine pump p1 (see also col. 8, lines 4+); c) “external heat exchanger” reads on heat exchanging section HS (see also col. 6, lines 44+); c) “pressurizing device” reads on high-pressure and low pressure gas supply sources GSHP and GSLP, respectively (see also col. 10, lines 50=)..

The claims are directed to an apparatus and NOT to a process. The structural elements of an apparatus are the physical elements present at the time the apparatus is taken off-the-shelf or removed from the shipping or storage container. In the instant application, the structural elements of the claimed apparatus are: an irradiation cell, a pump, an external heat exchanger and a pressurizing device.

Claims 2-6 and 22 are process limitations and not structural limitations of the claimed apparatus. Additionally, claim 1 recites statements of intended or desired use, including, “for producing a radioisotope from a target fluid ...”, “for generating flow of target fluid...”, etc. These process limitations clauses, as well as statements of intended use do not serve to patently distinguish the claimed structure over that of the reference, as long as the structure of the cited references is capable of performing the intended use. See MPEP 2111-2115.

See also MPEP 2114 that states:

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647.

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531.

[A]pparatus claims cover what a device is, not what a device does.” Hewlett-Packard Co. v. Bausch & Lomb Inc., 15 USPQ2d 1525,1528.

As set forth in MPEP 2115, a recitation in a claim to the material or article worked upon does not serve to limit an apparatus claim.

Any one of the systems in the cited references is capable of being used in the same manner and for the intended or desired use as the claimed invention. Note that it is sufficient to show that said capability exists, which is the case for the cited references.

As to claim 7, any one of Kiselev et al. or Stanton or Amini or Wieland et al. includes an irradiation cell comprising an inlet and outlet. As to the limitation, "to create a vortex in the flow of the target fluid inside the cavity", applicant has not defined the magnitude of the so-called vortex. Absent such definition, the examiner interprets the term broadly and reads it on any vortex level created inside the cavity. Any one of Kiselev et al. or Stanton or Amini or Wieland et al. inherently creates some level of vortex inside the cavity because of the fluid flow into said cavity. Such vortex creation cannot be prevented because of the fluid disturbance caused by the flow.

5. Claims 10-12, 14, 23-26 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Amini (U.S. 6,917,044).

As to claim 23, applicant's claim language reads on Amini as follows (e.g., see Fig. 1): a) "housing" reads on the combination of target body 11 and cooling flange 31; b) "window" reads on target window 14; c) "lateral wall portion" reads on the lateral wall of cooling flange 31 that surrounds target window 14; d) "second wall portion" reads on the wall of target body 11 that is adjacent target window 14; e) "inlet" and "outlet" read, respectively, on the inlet and outlet shown in the figure; f) "cavity" reads on the portion of cavity 10 that is disposed between irradiation window 14 and the wall of said target



Art Unit: 3663

window; g) "heat exchanger" reads on heat sinks 19 (see also col. 7, lines 1+); h) "pressurizing device" reads on heaters that inherently raise the pressure of the system (see also col. 7, lines 38+); i) "pump" reads on the inherent pump that feeds target fluid into cavity 10.

Claims 24 and 25 are process limitations and not structural limitations of the claimed apparatus. Amini is capable of being used in the same manner and for the intended or desired use as the claimed invention (see remarks in section 3 above that also applies here to Amini).

As to claim 26 and the limitation, "to create a vortex in the flow of the target fluid inside the cavity", applicant has not defined the magnitude of the so-called vortex. Absent such definition, the examiner interprets the term broadly and reads it on any vortex level created inside the cavity. Amini inherently creates a level of vortex inside the cavity because of the fluid flow into said cavity, and such vortex creation cannot be prevented.

As to claims 10 and 29, see Fig. 1 for a showing the inlet arranged so that the target fluid flow is directed an impact point of the accelerated charge particle beam in the irradiation window so that the inflow hits the window head-on with the beam.

As to claims 11 and 30, see Fig. 1 for a showing of the cavity having a central axis extending from the window 14 to the second wall portion, the outlet being connected indirectly to the lateral portion and the inlet along the central axis. Note that the claim recites "connected" (i.e. in the limitation, "outlet being connected to the lateral

wall portion") broadly. Such broad recitation includes "indirectly connected", which is the case for Amini's apparatus.

As to claims 12, 14, and 31, Amini discloses an internal cooling device through cooling flange 31 (see also col. 7, lines 55+). Note that the cooling flange indirectly cools cavity 10.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-7 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over one of Kiselev et al. or Stanton or Amini or Wieland et al. ('198).

In section 4 above, the examiner demonstrated that these process claims are met by the cited applied art because each one is capable of being used in the same manner and for the intended or desired use as the claimed invention. If applicant is of a different opinion, these claims are still unpatentable because they are obvious over said applied art.

The pump flow rate and the maximum temperature of the target fluid, as recited in claims 2-4, and the volume of the target fluid, as recited in claims 5 and 6, are matters that depend upon the design constraints imposed on the apparatus. Also the specific values for the parameters are subject to optimization, which includes the balancing of factors such as cost vs. operational performance, etc. As to matters of

Art Unit: 3663

optimization within prior art conditions or through routine experimentation, see MPEP 2144.05 II.A.

7. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being obvious over Amini.

In section 5 above, the examiner demonstrated that these process claims are met by the cited applied art because each one is capable of being used in the same manner and for the intended or desired use as the claimed invention. If applicant is of a different opinion, these claims are still unpatentable because they are obvious over said applied art. The limitations are matters of design and/or optimization within prior art conditions. See also section 6 above.

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amini in view of Wieland ("Foil Sealing Assembly used on 11 MeV Proton Targets, Proceedings of the First Workshop on Targetry and Target Chemistry, Heidelberg, Germany October 1985). Amini discloses the applicant's claim limitations except for the helium cooling.

Wieland teaches helium for cooling the target window of a device for producing radioisotopes from a target fluid (see page 14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use helium for cooling the irradiation window in the apparatus, as disclosed by Amini, because such modification is no more than the use of a well-known expedient of cooling an irradiation target by a well known cooling fluid within the nuclear art.

Art Unit: 3663

9. Claims 1-7, 10-12, 21-26 and 29-31 are under 35 U.S.C. 103(a) as being unpatentable over Shaeffer et al. (ORNL/MIT-258) in view of Amini. Shaeffer et al. disclose the applicant's claim limitations except for the details of the structure of the irradiation cell.

Shaeffer et al. disclose a device for F-18 production. Fig. 3 shows heat exchangers, a pump and pressurizing device (either the N<sub>2</sub> cylinder or the inherent heating of the target fluid that raises the system pressure).

They teach the target water entering at 40 °C and keeping the target water outlet below 90 °C. These temperatures meet the claimed limitation of "target fluid at a mean temperature below 130 °C" (see claims 2 and 24).

They also teach that target water flows at 0.5 gpm (or 1890 ml/min), which meets the claimed limitations of greater than 200 ml/minute, greater than 500 ml/minute and greater than 1000 ml/min (see claims 3, 4, 22 and 25).

They further teach a target fluid volume that is approximately 0.77 ml (see target dimensions shown in Fig. 1 and Table 5). This volume meets the claimed limitations of the target fluid volume in claims 5 and 6.

As to Shaeffer et al. meeting the above target fluid temperature, flow rate and volume limitations, note MPEP 2131.03, which states:

"[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art." *Titanium Metals Corp. v. Banner*; 778 F.2d 775, 227 USPQ 773.

Shaeffer et al. are silent about the specific details of the target capsule. However, as demonstrated in the previous sections, Amini teaches the claimed details regarding

Art Unit: 3663

the irradiation cell comprising a window and a metallic insert having a housing with a lateral wall and second wall portion as recited in the claims (e.g., claims 1 and 23).

Amini also teaches the configuration of the inlet and outlet for cooling, as well as the head-on configuration of charged particle beam and the target fluid inflow, as recited in the claims (e.g., claims 7, 10, 11, 12 and 29-31).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus, as disclosed by Shaeffer et al., to have the specific structure of the irradiation cell, as taught by Amini, to gain the advantages thereof (i.e., high power, high yield target), because such modification is no more than the use of a well known expedient within the nuclear art.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaeffer et al., in view of Amini, as applied to claims 1-7, 10-12, 21-26 and 29-31 above, and further in view of Wieland ("Foil Sealing Assembly used on 11 MeV Proton Targets", Proceedings of the First Workshop on Targetry and Target Chemistry, Heidelberg, Germany October 1985). The Shaeffer et al.-Amini combination discloses the applicant's claim limitations except for the helium cooling.

Wieland teaches helium for cooling the target window of a device for producing radioisotopes from a target fluid (see page 14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use helium for cooling the irradiation window in the apparatus, as disclosed by the Shaeffer et al.-Amini combination, because such modification is no more than the use of a well-known

Art Unit: 3663

expedient of cooling an irradiation target by a well known cooling fluid within the nuclear art.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reference E further illustrate prior art.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rick Palabrica whose telephone number is 571-272-6880. The examiner can normally be reached on 6:00-4:30, Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jack Keith can be reached on 571-272-6878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/537,975  
Art Unit: 3663

Page 14

August 11, 2008

/Rick Palabrica/  
Primary Examiner, Art Unit 3663